CARFDEXALENA Regimen
Carfilzomib, Dexamethasone, Lenalidomide

Disease Site: Hematologic - Multiple Myeloma

Intent: Palliative

Regimen Category: Evidence-Informed
Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

Rationale and Uses: For the treatment of patients with relapsed multiple myeloma, with good performance status and adequate renal function, who have received at least 1 prior treatment.

Refer to NDFP form for details on other funding criteria, especially for patients who were previously on lenalidomide-based or bortezomib-based treatments.

Supplementary Public Funding: carfilzomib
New Drug Funding Program (Carfilzomib (Triplet Therapy) - In Combination with Lenalidomide and Dexamethasone for Relapsed Multiple Myeloma) (Funded by NDFP for up to 18 cycles )

dexamethasone
ODB - General Benefit (dexamethasone) (tablets )
**B - Drug Regimen**

**Cycle 1:**

- **carfilzomib** 20 mg /m² IV Days 1, 2
- **carfilzomib** 27 mg /m² IV Days 8, 9, 15, 16
- **dexamethasone**^ 40* mg /day IV / PO Days 1, 8, 15, 22
- **lenalidomide** 25** mg /day PO Days 1 to 21

**Cycles 2 to 12:**

- **carfilzomib** 27 mg /m² IV Days 1, 2, 8, 9, 15, 16
- **dexamethasone**^ 40* mg /day IV / PO Days 1, 8, 15, 22
- **lenalidomide** 25** mg /day PO Days 1 to 21

**Cycles 13 to 18#:**

- **carfilzomib** 27 mg /m² IV Days 1, 2, 15, 16
- **dexamethasone**^ 40* mg /day IV / PO Days 1, 8, 15, 22
- **lenalidomide** 25** mg /day PO Days 1 to 21

(Continued on next page)
Cycle 19 onwards# Report as regimen code DEXALENA:

**dexamethasone^**

40* mg /day IV / PO Days 1, 8, 15, 22

(*Outpatient prescription in 4 mg tablets for patients on PO route)

**lenalidomide**

25** mg /day PO Days 1 to 21

(**Outpatient prescription in 5 mg, 10 mg, 15 mg or 25 mg capsules)

Lenalidomide may only be prescribed and dispensed by physicians and pharmacists registered with RevAid®. Patients must also be registered and meet all conditions of the RevAid® program.

^In elderly patients, the dexamethasone dose should be reduced (i.e. to 20 mg once weekly).

# per Stewart 2015

C - Cycle Frequency

**REPEAT EVERY 28 DAYS**

Unless disease progression or unacceptable toxicity occurs.

D - Premedication and Supportive Measures

**Antiemetic Regimen:** Low

**Other Supportive Care:**

Also refer to CCO Antiemetic Summary

**Lenalidomide:**

- Patients must also be registered and meet all conditions of the RevAid® program, including contraception.

- Patients at risk of tumour lysis syndrome should have appropriate prophylaxis and be
Prophylaxis for venous thromboembolism is recommended in patients at risk (also see supportive care for carfilzomib with dexamethasone.)

Careful consideration and monitoring must be taken with erythropoietin stimulating agents (ESAs), since the concomitant use of ESAs with lenalidomide may potentiate the risk of thrombosis.

Optimal control of thyroid function is recommended prior to starting treatment.

Carfilzomib:

- Consider the use of antiviral prophylaxis during carfilzomib therapy to decrease the risk of herpes zoster reactivation.

- Thromboprophylaxis is recommended in patients being treated with carfilzomib in combination with dexamethasone. The choice of agent should be based on patient risk factors and clinical status.

- Hypertension should be well-controlled prior to initiation of treatment with carfilzomib.

- Adequate hydration is required prior to dosing in cycle 1, especially in patients at high risk for tumour lysis syndrome or renal toxicity. The total fluid volume may be adjusted as clinically indicated in patients with baseline or at high risk of cardiac failure.

- Cycle 1:
  - oral fluids (30 mL/kg/day for 48 hours before start of cycle)
  - 250-500 mL of IV fluid before and after each dose (if needed)

- Subsequent cycles:
  - continue oral and/or IV hydration as needed

- Dexamethasone IV/PO should be given at least 30 minutes, but no more than 4 hours before carfilzomib.

E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated. Patients with a body surface area (BSA) > 2.2 m² should be dosed based on a maximum BSA of 2.2 m². Dose adjustments for carfilzomib do not need to be made for weight changes ≤ 20%.

Women of child bearing potential must have two negative pregnancy tests before initiating...
Dosage with toxicity

**Hematologic Toxicity:**

<table>
<thead>
<tr>
<th>Toxicity (counts x 10^9/L)</th>
<th>Carfilzomib</th>
<th>Lenalidomide</th>
<th>Dexamethasone</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st instance: platelets &lt; 30*</td>
<td>If platelets 10-30 without evidence of bleeding, maintain full dose.</td>
<td>Hold until platelets ≥ 30, then resume at one dose level reduction.</td>
<td>No change</td>
</tr>
<tr>
<td>Subsequent instances: platelets &lt; 30*</td>
<td>If platelets 10-30 without evidence of bleeding, maintain full dose.</td>
<td>Hold until platelets ≥ 30, then resume at one further dose level reduction.</td>
<td>No change</td>
</tr>
<tr>
<td>1st instance: ANC &lt; 1</td>
<td>If ANC 0.5-1, continue at full dose.</td>
<td>Hold, add G-CSF, and resume at full dose when ANC ≥ 1</td>
<td>No change</td>
</tr>
<tr>
<td>Subsequent instances: ANC &lt; 1</td>
<td>If ANC 0.5-1, continue at full dose.</td>
<td>Hold, add G-CSF, and resume at one dose</td>
<td>No change</td>
</tr>
</tbody>
</table>
If ANC < 0.5, hold until ANC ≥ 0.5, then resume at one dose level reduction.

*A lower threshold of 20 x 10^9/L may be considered for lenalidomide dose reductions for patients with myeloma involvement in the bone marrow > 50%*

### Non-hematologic toxicities

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Carfilzomib</th>
<th>Lenalidomide</th>
<th>Dexamethasone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edema &gt; grade 3 (limiting function and unresponsive to therapy or anasarca)</td>
<td>n/a</td>
<td>n/a</td>
<td>Diuretics as needed, and resume at one dose level reduction. If persists, decrease by one further dose level. If persists despite second reduction, discontinue.</td>
</tr>
<tr>
<td>Muscle weakness &gt; grade 2</td>
<td>n/a</td>
<td>n/a</td>
<td>Decrease by one dose level reduction. If persists, decrease by one further dose level. If persists despite second reduction, discontinue.</td>
</tr>
<tr>
<td>Grade 2 to 3 rash</td>
<td>Grade 3: If related to carfilzomib, follow actions for ≥ grade 3 non-hematologic toxicity</td>
<td>Hold or consider discontinuing.</td>
<td>n/a</td>
</tr>
<tr>
<td>Angioedema OR Grade 4 skin rash OR Exfoliative or bullous rash OR Suspected Stevens Johnson Syndrome, Toxic epidermal necrolysis or DRESS</td>
<td>Discontinue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 3 or 4 cardiac events</td>
<td>Hold until resolved. Consider risk vs.</td>
<td>Hold until resolved. Consider risk vs.</td>
<td>n/a</td>
</tr>
<tr>
<td>Condition</td>
<td>Action</td>
<td>Action</td>
<td>Action</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Hypertensive crisis/emergency</td>
<td>Hold until resolves or under control. Consider the risk vs. benefit of restarting; consider dose reduction.*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>ARDS, ILD, pneumonitis, pulmonary hypertension, grade 3 or 4 dyspnea</td>
<td>Hold until resolves. Consider the risk vs. benefit of restarting.</td>
<td>For suspected pneumonitis, hold and investigate; discontinue if confirmed.</td>
<td>n/a</td>
</tr>
<tr>
<td>Any ≥ grade 3 non-hematologic toxicity¹,²</td>
<td>Hold then resume at full dose when toxicity has resolved to ≤ grade 2 or baseline. Consider dose reduction. If tolerated, the reduced dose may be increased to the previous dose.</td>
<td>Hold then resume at one dose level reduction when toxicity has resolved to ≤ grade 2 or baseline.</td>
<td>Hold then resume at one dose level reduction when toxicity has resolved to ≤ grade 2 or baseline. If recurs, discontinue.</td>
</tr>
<tr>
<td>Thrombotic microangiopathy (including TTP/HUS)</td>
<td>Hold and evaluate; discontinue if confirmed.</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>PRES</td>
<td>Hold and investigate; discontinue if</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>
In the event of possible drug-related non-hematologic toxicity, the physician should determine causality to the affected agent(s) and the recommended action(s) for each should be instituted.

Carfilzomib, lenalidomide and dexamethasone do not need to be held in the following cases: grade 3 nausea, vomiting or diarrhea (unless persisting more than 3 days with adequate treatment of antiemetics or antidiarrheals); grade 3 dexamethasone-related hyperglycemia; grade 3 fatigue (unless persisting for > 14 days)

*discontinue in patients receiving 15 mg/m²

Renal toxicity during treatment

<table>
<thead>
<tr>
<th>Carfilzomib</th>
<th>Lenalidomide</th>
<th>Dexamethasone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum creatinine ≥ 2 x baseline, or CrCl &lt; 15 mL/min (or CrCl decreases to ≤ 50% of baseline) or need for dialysis: Hold and resume at one dose level reduction when renal function has recovered to within 25% of baseline. If tolerated, the reduced dose may be increased to the previous dose.</td>
<td>Hold until CrCl recovers to baseline, then resume at one dose level reduction. If recurs, reduce dose to 15 mg q 48 hours. If dialysis required, reduce dose to 5 mg once daily and administer after dialysis.</td>
<td>No change</td>
</tr>
</tbody>
</table>

Hepatic Impairment

<table>
<thead>
<tr>
<th>Impairment</th>
<th>Carfilzomib Starting Dose</th>
<th>Lenalidomide Starting Dose</th>
<th>Dexamethasone Starting Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild (bilirubin &gt; 1 - &lt;1.5 x ULN or AST &gt; ULN) or Moderate (bilirubin &gt; 1.5 - &lt;3 x ULN)</td>
<td>Reduce dose by 25%</td>
<td>No dosage adjustment necessary</td>
<td>No dosage adjustment necessary</td>
</tr>
<tr>
<td>Severe (bilirubin &gt; 3 x ULN)</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
</tr>
</tbody>
</table>
**Renal Impairment**

**Pre-existing renal impairment**

<table>
<thead>
<tr>
<th>Creatinine Clearance (mL/min)</th>
<th>Carfilzomib</th>
<th>Lenalidomide</th>
<th>Dexamethasone</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 50</td>
<td>No dose adjustment is required for carfilzomib in patients with baseline renal impairment.</td>
<td>No change</td>
<td>No change</td>
</tr>
<tr>
<td>30 to 49</td>
<td>Reduce dose to 10 mg daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 30</td>
<td>Reduce dose to 15 mg q 48 hours. If dialysis required, reduce to 5 mg daily and give post-dialysis.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Patients with a CrCl < 50 mL/min were excluded from the pivotal Phase 3 trial.

**Dosage in the Elderly**

There were no differences in effectiveness of **carfilzomib**, in combination with lenalidomide and dexamethasone, in any of the studied age groups. Patients aged 65 years or more, especially those more than 75 years, had more serious adverse events, including cardiac events.

The incidences of serious and non-serious adverse events are significantly higher in patients > 65 years with **lenalidomide** and this may be related to renal impairment. Monitor elderly patients closely, especially cardiac and renal function. Dose modification based on degree of renal impairment is required.
F - Adverse Effects

Refer to carfilzomib, lenalidomide and dexamethasone drug monograph(s) for additional details of adverse effects

<table>
<thead>
<tr>
<th>Common (25-49%)</th>
<th>Less common (10-24%)</th>
<th>Uncommon (&lt; 10%), but may be severe or life-threatening</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Fatigue</td>
<td>- Dizziness</td>
<td>- Pancreatitis</td>
</tr>
<tr>
<td>- Diarrhea</td>
<td>- Edema - limbs</td>
<td>- GI perforation</td>
</tr>
<tr>
<td>- Infusion-related reactions</td>
<td>- Rash (may be severe; SJS, TEN, DRESS)</td>
<td>- Renal failure</td>
</tr>
<tr>
<td>- Abnormal electrolyte(s)</td>
<td>- Constipation</td>
<td>- Peripheral neuropathy</td>
</tr>
<tr>
<td>- Myelosuppression ± infection (includes atypical, viral</td>
<td>- Insomnia</td>
<td>- Cardiotoxicity</td>
</tr>
<tr>
<td>reactivation), bleeding (may be severe)</td>
<td>- Dyspnea</td>
<td>- Hypotension</td>
</tr>
<tr>
<td>- Musculoskeletal pain (including spasms)</td>
<td>- Hypertension (may be severe)</td>
<td>- Tumor lysis syndrome</td>
</tr>
<tr>
<td>- Cough, dyspnea</td>
<td>- Dyspepsia</td>
<td>- Arterial thromboembolism</td>
</tr>
<tr>
<td>- Fever</td>
<td>- Venous thromboembolism (may be severe)</td>
<td>- Adult respiratory distress syndrome (ARDS)</td>
</tr>
<tr>
<td>- Headache</td>
<td>- Hyperglycemia</td>
<td>- Cholecystitis</td>
</tr>
<tr>
<td>- Nausea, vomiting</td>
<td>- Steroid effects</td>
<td>- Hemorrhage</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Pneumonitis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Pulmonary hypertension</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Thrombotic microangiopathy (includes TTP, HUS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- ↑ LFTs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Rhabdomyolysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- PRES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Increased QTc</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Atrial fibrillation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Blurred vision, cataract</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Hyper/hypothyroidism</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Solid organ transplant rejection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- GVHD or transplant rejection</td>
</tr>
</tbody>
</table>

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G - Interactions

Refer to carfilzomib, lenalidomide and dexamethasone drug monograph(s) for additional details

- Carfilzomib dose not induce, but may inhibit, CYP3A4/5.
- Caution with P-glycoprotein substrates (i.e. verapamil, digoxin, morphine, ondansetron) and monitor digoxin levels when given with carfilzomib.
- Caution and consider non-hormonal method(s) of contraception as use of oral contraceptives or other hormonal methods of contraception may have reduced efficacy and may increase the risk of blood clots.
- Lenalidomide can increase the concentration of digoxin. Use caution and monitor digoxin levels.
- Lenalidomide increases risk of thromboembolic events and would have an additive effect if co-administered with other thromboembolic agents.

H - Drug Administration and Special Precautions

Refer to carfilzomib, lenalidomide and dexamethasone drug monograph(s) for additional details

Administration:

Carfilzomib

- Carfilzomib should be given as a 10 minute infusion
- May further dilute dose in 50-100 mL D5W. Do not dilute in NS for IV administration.
- Carfilzomib should not be administered as an IV bolus. Maybe administered directly by IV infusion or in an IV bag.
- Flush line before and after carfilzomib administration with NS or D5W.
• After reconstitution, gently swirl and/or invert the vial slowly for 1 minute. Do not shake.

• If foaming occurs, allow the solution to settle in the vial until foaming subsides (approximately 5 minutes) and the solution is clear, colourless and free of visible particulates.

• Stable in D5W. Do not mix with or administer as an infusion with other medications.

• The time from reconstitution to administration should not exceed 24 hours.

• Unreconstituted carfilzomib powder for injection should be stored in unopened vials at 2–8°C.

**Lenalidomide**

• Oral self-administration; swallow capsules whole; they should not be broken, chewed, or opened. Do not extensively handle the capsules.

• Give capsules preferably with water, either with or without food. Do not remove from blister packs until ready to take the dose.

• Females who could become pregnant, or who plan to become pregnant can handle lenalidomide capsules if they are using latex gloves.

• If a dose is missed, it may be taken up to 12 hours after the time it is normally taken. Otherwise, skip this and take the next dose on the following day at its usual scheduled time.

• Store capsules at room temperature (15 to 30°C)

• Drug available by outpatient prescription in pharmacy registered with the RevAid® program. Please call 1-888-RevAid-1 or log onto [www.RevAid.ca](http://www.RevAid.ca)

**Dexamethasone**

• Oral self-administration or may be given by IV route on carfilzomib clinic days.

• Give tablets with food, preferably in the morning.

**Contraindications:**

• Patients who have a hypersensitivity to these drugs or any of their components

• Pregnant or breastfeeding women

• Women at risk of being pregnant and male patients who do not comply with contraception requirements (see Pregnancy section in [lenalidomide](http://lenalidomide) drug monograph for additional details)
Other Warnings/Precautions:

Carfilzomib

- Use with caution in patients on a controlled sodium diet. Each mL contains 0.3 mmol (7 mg) of sodium.

- The risk of heart failure is increased in elderly patients (≥ 75 years). Patients with NYHA Class III/IV heart failure, recent MI, conduction abnormalities, angina or arrhythmias uncontrolled by medications were not eligible for carfilzomib-based clinical trials. These patients may be at greater risk of cardiac complications and should have their medical management optimized, including hypertension, prior to starting treatment with carfilzomib and monitored closely throughout.

- Caution with driving or using machinery as fatigue, dizziness and a drop in blood pressure may occur with treatment.

Lenalidomide

- Contains lactose; carefully consider use in patients with hereditary galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption.

- Use with caution and consider venous thromboembolism prophylaxis when used in combination with corticosteroids or thrombogenic agents, such as hormones and erythropoietin (see Adverse Effects section in lenalidomide drug monograph for additional details).

- Exercise caution in patients with risk factors for arterial thromboembolism (e.g. hypertension and hyperlipidemia), or risk factors for atrial fibrillation (e.g. electrolyte abnormalities, pre-existing heart disease, hypertension, infection).

- Use with caution in patients with high tumour burden; monitor closely and use appropriate precautions for tumour lysis syndrome.

- Use with caution and monitor closely in patients with previous viral infections such as HBV and herpes zoster.

Pregnancy and Lactation:

- Lenalidomide is contraindicated in pregnancy and in females and males of childbearing potential who do not comply with the contraception conditions of the RevAid® program. See the lenalidomide drug monograph for details.

- Carfilzomib and dexamethasone are not recommended for use in pregnancy.
Adequate contraception should be used by female patients and/or their male partners during carfilzomib treatment, and for 30 days after the last dose.

Adequate contraception should be used by male patients and/or their female partners during carfilzomib treatment, and for 90 days after the last dose.

- Breastfeeding is contraindicated.

I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Recommended Clinical Monitoring

- Blood pressure; Baseline and before each treatment
- CBC with differential; Baseline and before each treatment week
- Electrolytes, including potassium; Baseline and before each cycle
- Liver and renal function tests; Baseline and before each cycle
- Thyroid function tests; Baseline and as clinically indicated
- Blood glucose levels; Baseline and as clinically indicated
- Specific to lenalidomide: RevAid® requirements regarding pregnancy tests for women of child-bearing potential; Before starting and as indicated per RevAid®
- Cancer screening for occurrence of second primary malignancy; assess risk prior to starting treatment, then at each visit or as clinically indicated
- Clinical toxicity assessment and grading of cardiac, gastrointestinal, neurologic and respiratory symptoms, rash, fatigue, infection (including viral reactivation), infusion reactions, bleeding, tumour lysis syndrome, arterial and venous thromboembolism, GVHD and organ transplant rejection (if applicable); At each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

- ECG; Baseline; repeat if arrhythmia suspected
INR in patients receiving warfarin; Baseline and as clinically indicated
LVEF assessment (especially in patients ≥ 75 years, or those at greater risk for cardiac complications); Baseline and as clinically indicated

J - Administrative Information

lenalidomide, dexamethasone po - Outpatient prescription for home administration

Approximate Patient Visit
First cycle: 12 hours (includes pre- and post-IV hydration); Cycles 2 to 12: 3 hours (if no IV hydration); Cycles 13 to 18: 2 hours

Pharmacy Workload (average time per visit) 19.850 minutes
Nursing Workload (average time per visit) 42.417 minutes

K - References

Carfilzomib, lenalidomide drug monographs, Cancer Care Ontario.

PEBC Advice Documents or Guidelines

Treatment of Multiple Myeloma: ASCO and CCO Joint Clinical Practice Guideline

October 2019 Added note on dexamethasone dose in the elderly; added PEBC guideline link; updated supportive care, dose modifications, adverse effects, interactions, special precaution and monitoring sections

M - Disclaimer

Regimen Abstracts
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Regimen Monographs

Refer to the New Drug Funding Program or Ontario Public Drug Programs websites for the most up-to-date public funding information.

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